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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/972,741	10/05/2001	Keith Allen	R-723-CIP	5377

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DELTAGEN, INC.
740 Bay Road
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EXAMINER

QIAN, CELINE X

ART UNIT	PAPER NUMBER
1636	13

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/972,741

Applicant(s)

ALLEN, KEITH

Examiner

Celine X Qian

Art Unit

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 8-16, 18, 19, 24-45, 47 and 52-72 is/are pending in the application.
- 4a) Of the above claim(s) 11-16, 24-44 and 53-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8-10, 18, 19, 45 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Claims 1-4, 8-16, 18, 19, 24-45, 47 and 52-72 are pending in the application. Claims 11-16, 24-44 and 53-72 are withdrawn from consideration for being directed to non-elected subject matter. Claims 1-4, 8-10, 18, 19, 45, 47 and 52 are currently under examination.

This Office Action is in response to the Amendment filed on 6/23/03.

Response to Amendment

The status of claim 52 is unclear because it was not marked as cancelled or pending in the claim list. However, Applicant indicates that it is cancelled on page 10 of the Amendment. Clarification of the status of the claim in the response to this office action is required.

The objection to claim 2 has been withdrawn in light of Applicant's amendment of the claims.

The rejection of claims 1-4, 8-10, 18, 19, 45, 47 and 52 under 35 U.S.C.112 1st paragraph (written description and enablement) has been withdrawn in light of Applicant's amendment of the claims.

The rejection of claims 1-4, 9, 10 and 23 under 35 U.S.C.112 2nd paragraph has been withdrawn in light of Applicant's amendment of the claims.

The rejection of claims 8 and 10 under 35 U.S.C.103 (a) has been withdrawn in light of Applicant's amendment of the claims.

The rejection of claims 18 and 19 under provisional double patenting has been withdrawn in light of Applicant's submission of terminal disclaimer.

Claims 1-4 stand rejected under 35 U.S.C.103 (a) for reasons set forth of the record mailed on 12/18/02 and further discussed below.

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Claims 8-10, 18, 19, 45 and 47 are rejected under 35 U.S.C. 112 2nd paragraph for reasons discussed below.

Response to Arguments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mansour et al (1988, Nature, vol. 336, No. 24, 348-352), in view of Kato et al. (1994, Gene, vol. 145, 311-312) and Travis et al. (1997, PNAS, vol. 94, 11055-11060).

In response to the rejection, Applicant argues that the combination of the references do not teach all the claim limitations. Applicants argues none of the references teach a transgenic mouse having a disruption in the magnesium dependent phosphatase gene, and the references further fail to teach a transgenic mouse exhibits the claimed phenotype. Therefore, Applicant concludes that the claimed invention is not obvious.

Applicant's argument has been fully considered but deemed unpersuasive. The claims are drawn to a magnesium-dependent phosphatase gene-targeting construct and a method of making said construct. The recitation of "wherein the target construct when...exhibits...a phenotypic abnormality selected from the group consisting of a lung abnormality, elevated white blood cell counts..." defines the intended use of the knockout construct, which does not carry patentable weight. In response to applicant's argument that none of the references teach or

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suggest a transgenic mouse having magnesium-dependent phosphatase gene disruption, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one of ordinary skill in the art would have been motivated to knockout the expression of the magnesium-dependent phosphatase gene in a mouse to study the function of this gene and to develop specific inhibitors for this phosphatase which may be useful in treating cystic fibrosis, as suggested by the teaching of Travis et al. Therefore, it would have been obvious to the ordinary artisan to make a targeting construct as claimed. As discussed in the previous office action, one of ordinary skill of art would have reasonable expectation of success to make such targeting construct based on the teaching of Mansour and Kato references. Therefore, the claimed targeting construct is obvious based on the teaching of the Mansour, Kato and Travis et al.

New Grounds of Rejection Necessitated by Applicant's Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-10, 18, 19, 45 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 8-10, 18, 19, 45 and 47, the recitation of “a transgenic mouse comprising a disruption in a magnesium-dependent protein phosphatase represented by SEQ ID NO:1” renders the claims indefinite. SEQ ID NO:1 is a nucleic acid sequence encoding the magnesium-dependent phosphatase. Therefore, the disruption is in the magnesium-dependent protein phosphatase gene rather than the protein. In addition, the recitation of “functional protein encoded by the a magnesium-dependent protein phosphatase gene” on line 4 appears to have grammatical error. Appropriate correction is required.

Claim 10 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: 1) selecting the embryonic stem cell comprising a disruption in the magnesium-dependent phosphatase gene; 2) further breeding the heterozygous transgenic mouse to obtain a homozygous transgenic mouse.

Regarding claim 19, the recitation of “consistent a symptom” should be consistent with a symptom.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

This application contains claims 11-16, 24-44 and 53-72 drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.

Anne-Marie Falk
ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER